UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,229	08/26/2003	Charles R Wescott	10280-077002	6199

26161 7590 08/12/2008
FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
08/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,229	WESCOTT ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-57 and 59-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-57 and 59-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. All rejections made in the office action dated March 20, 2006 and not cited herein are hereby withdrawn.

Election/Restrictions

2. Applicant's election without traverse of Group III, drawn to cyclic peptides of SEQ ID NO. 89, with the election of species as SEQ ID NO:97, in the reply filed on 3-19-08 is acknowledged.

In accordance with Markush and species practice, a search for SEQ ID 97 was conducted and it was found to be allowable. The search was then extended to the other species and finally to the genus and they too were found to be free of the prior art. An office action on the merits follows below regarding 112 First paragraph issues.

New Matter

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 54-57 and 59-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states "While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

See MPEP 2163. Thus, the claimed invention must have written description in the originally filed disclosure. To comply with written description, the Federal Circuit has stated that the specification "must. . .convey with reasonable clarity to those skilled in the art that . . .[the applicant] was in possession of the invention." *Purdue Pharma L.P. v. Faulding, Inc.* 230 F.3d 1320, 1323 (Fed. Cir. 2000). It is a question whether Applicant necessarily discloses the particular claimed invention in the later filed application. "[T]he test ... is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application." *Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed.Cir. 204). The same standards govern whether new matter has been added to the specification.

In the instant case, the claims have been amended to recite a generic sequence of SEQ ID 89 of the formula Cys-Pro-Tyr-Xaa-Leu-Cys, and SEQ ID 135 of the formula X1-X2-Cys-Pro-X6-Leu-Cys-X9-X10-X11, where the cysteines form, presumably, a disulfide bridge. These generic sequences and the cyclized species falling within the scope are not supported by the original filed disclosure. It is unquestionable that the sequences as currently recited and with the sequence identifiers as claimed, were not **explicitly** recited in the originally filed specification. The originally filed sequence listing ended with SEQ ID NO 72. Further the only cyclized peptides explicitly shown in the originally filed disclosure are recited in table 12 of the specification, which are cyclized through an amide linkage and generic cyclic CXYYGTC peptide cyclized through a disulfide linkage. Thus, the claimed sequences are not supported by an explicit disclosure.

Furthermore, the claimed invention is not supported implicitly. The originally filed disclosure, when discussing the sequences containing the motif Cys-X4-X5-Tyr-X7-X8-Cys, states that the cysteine resides of "the polypeptides are believed to form a disulfide bond, which causes the polypeptides to form a stable loop or cyclic structure under non-reducing conditions."

However, this discussion is confined only to the peptide of SEQ ID NO 1. (see page 18 of the specification). When discussing SEQ ID NO 20, the sequence that corresponds to the linear counter part of SEQ ID 89, the originally filed disclosure fails to provide any discussion regarding the formation of a disulfide bridge or a stable loop. It is acknowledged that the specification recites the peptide as "fibrin binding loop." However, the specification never makes clear that the fibrin binding loop is indeed defined only as cyclized peptide. Rather, one of ordinary skill in the art is given the opposite perception since the originally filed sequence listing identified all the peptides that are "fibrin binding loop" peptides as linear peptides.

Moreover, it is acknowledged that the specification generally states the fibrin binding polypeptides may be conformationally restrained by disulfide linkage between two cysteine residues in their sequence. (see page 22 of the specification) This, however, does not provide support for cyclizing the "fibrin biding loop peptides." The fibrin binding polypeptides are defined by SEQ ID NO 1. When discussing SEQ ID 20, the specification fails to state that these are "fibrin binding polypeptides" within the meaning of the specification and thus are encompassed by the statements made on page 22 for cyclizing. As further support for this conclusion, the specification describes cyclization of specific peptides having the motif Cys-Xaa-Tyr-Tyr-Gly-Thr-Cys in example 4. This sequence corresponds and falls within the markush group of the "fibrin binding polypeptides" of SEQ ID 1, disclosed in page 18 of the specification. Indeed all of the species disclosed in table 2 of the specification correspond to SEQ ID NO 1 of the originally filed disclosure, which were taught as being cyclized and are "fibrin binding polypeptides." None of the species disclosed in the specification correspond to the generic SEQ ID NO 20. Thus, one of ordinary skill in the art could not arrive at implicit support for the claimed invention. Again it is asserted, "[o]ne skilled in the art,

reading the original disclosure, must immediately discern the limitation at issue in the claims." *Purdue Pharma*, 230 F.3d at 1323.

Thus, the claimed invention lacks written description in the originally filed disclosure and constitutes new matter.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654